

# Notice of Allowability

Application No.

09/813,492

Examiner

Anne Holleran

Applicant(s)

LABOW ET AL.

Art Unit

1642

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/24/2004.
2. ☒ The allowed claim(s) is/are 1,7-11, and 16.
3. ☒ The drawings filed on 21 March 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 7/2/2004.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

*am Harris*  
ANNA M. HARRIS, PH.D.  
PRIMARY EXAMINER  
8/17/2004

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### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Regina Bautista on July 2, 2004.

The application has been amended as follows:

Claims 3-5 (withdrawn, election without traverse in paper filed 7/30/2002) and 17 were canceled without prejudice.

Claim 1 (three times amended) A method for detecting [a polynucleotide in a breast sample] the presence of a breast tumor comprising the steps of:

a) providing a probe, wherein said probe comprises at least 10 consecutive nucleotides in length, and which hybridizes to a nucleic acid sequence [comprising] consisting of SEQ ID NO: 1;

b) contacting [said] a breast sample with said probe and

c) quantifying the level of hybridization of said probe [thereby determining the presence or amount of said polynucleotide in said sample] wherein [suppressed] reduced levels of hybridization to a sequence comprising SEQ ID NO: 1 compared to control levels in surrounding breast tissue samples indicates the presence of a breast tumor.

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Claim 7 (twice amended) A method for detecting a breast tumor in a subject characterized by [an altered] a reduced level of expression of Mammary gland Enriched Chemokine (MEC), wherein MEC is encoded by SEQ ID NO: 1, comprising: (a) contacting a breast sample [expressing mRNA polynucleotides] with a probe that hybridizes to a nucleic acid sequence consisting of SEQ ID NO: 1 or to [a] the full complement thereof; and (b) measuring the hybridization level of said probe to [said polynucleotides] a polynucleotide comprising SEQ ID NO: 1 or to a polynucleotide comprising a full complement of SEQ ID NO: 1, wherein [reduced] a reduction or loss of [said mRNA expression] hybridization levels compared to hybridization levels in breast samples without tumors or to levels in tissue surrounding the location of [said] a breast tumor indicates the presence of a breast tumor in said subject.

Claim 8 (amended) The method of claim 7, wherein said measuring step [is performed by] comprises Northern blot analysis, polymerase chain reaction (PCR), reverse transcriptase PCR, or in situ hybridization.

Claim 16 (twice amended) A method for detecting a breast tumor in a patient, comprising the steps of:

a) providing a probe, the nucleotide sequence of which consists of SEQ ID NO: 1 or a fragment thereof of at least 10 consecutive nucleotides;

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b) contacting said probe to a sample of breast tissue or breast tissue extract from said patient, wherein the sampld breast tissue is suspected of having a tumor, to permit hybridization of said probe to mRNA encoding a protein encoded by SEQ ID NO: 1 and

c) quantifying the level of hybridization of said probe to said mRNA wherein [reduced] reduction or loss of hybridization levels [said mRNA expression levels] in the sample compared to levels of hybridization of said probe to said mRNA in breast tissue adjacent to the location of said sample [of breast tissue or breast tissue extract from said patient] indicates the presence of a breast tumor in said patient.

The following is an examiner's comment: The probe of claim 1 hybridizes to a sequence consisting of SEQ ID NO: 1, but the detection step comprises detecting a polynucleotide comprising SEQ ID NO: 1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran  
Patent Examiner  
July 2, 2004